

AMENDED IN SENATE MAY 10, 2005

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL

No. 798

Introduced by Senator Simitian

February 22, 2005

An act to add Division 115 (commencing with Section 150000) to the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 798, as amended, Simitian. Prescription drugs: collection and distribution program.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would ~~specify requirements of a program established by a county under these provisions, including, among others, for procedures that ensure the~~ *require a county that elects to establish a repository and distribution program to establish procedures for, at a minimum, (1) establishing eligibility for medically indigent patients who may participate in the program, (2) ensuring that eligible patients are not charged for any medications provided under the program, (3) ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist, and (4) ensuring the privacy of individuals for whom the medication was originally*

prescribed. The bill would authorize any drug manufacturer legally authorized under federal law to manufacture or sell pharmaceutical drugs, licensed health facility, or pharmacy to donate medications pursuant to these provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Division 115 (commencing with Section
2 150000) is added to the Health and Safety Code, to read:

3
4 DIVISION 115. SURPLUS MEDICATION COLLECTION
5 AND DISTRIBUTION
6

7 150000. It is the intent of the Legislature in enacting this
8 division to authorize the establishment of a voluntary drug
9 repository and distribution program for the purpose of
10 distributing surplus medications to persons in need of financial
11 assistance to ensure access to necessary pharmaceutical
12 therapies.

13 150002. A health facility licensed under Chapter 2
14 (commencing with Section 1250) of Division 2, a pharmacy
15 licensed pursuant to Chapter 9 (commencing with Section 4000)
16 of Division 2 of the Business and Professions Code, and a drug
17 manufacturer that is legally authorized under federal law to
18 manufacture and sell pharmaceutical drugs, may donate excess or
19 surplus unused prescribed medications under a program
20 established by a county pursuant to this division.

21 150004. (a) A county may establish, by local ordinance, a
22 repository and distribution program for purposes of this division.

23 (b) A county that elects to establish a repository and
24 distribution program pursuant to this division shall establish
25 procedures for, at a minimum, all of the following:

26 (1) Establishing eligibility for medically indigent patients who
27 may participate in the program.

28 (2) Ensuring that patients eligible for the program shall not be
29 charged for any medications provided under the program.

30 (3) Ensuring proper safety and management of any
31 medications collected by and maintained under the authority of a

1 licensed pharmacist by ensuring, at a minimum, all of the
2 following:

3 (A) That only those drugs that are received and maintained in
4 their unopened, tamper-evident packaging are dispensed.

5 (B) That any drugs received have not been adulterated,
6 misbranded, or stored under conditions contrary to standards set
7 by the United States Pharmacopoeia or the product manufacturer.

8 (C) That any drugs received are dispensed prior to their
9 expiration date.

10 (D) That reasonable methods have been established to ensure
11 that drugs received have not been in the possession of any
12 individual member of the public.

13 (E) That a pharmacist may use his or her discretion and best
14 judgment in deciding whether or not to accept any donated drug.

15 (F) That records are kept for at least three years from the date
16 that any drug is received or dispensed, whichever is later,
17 pursuant to this division.

18 *(G) That pharmacists adhere to standard pharmacy practices*
19 *as required by state and federal law when dispensing all*
20 *prescription drugs, including narcotics and other controlled*
21 *substances.*

22 *(H) That donated drug stock is stored separately from a*
23 *pharmacy's general supply for inventory, accounting, and*
24 *inspection purposes.*

25 *(I) That any county that elects to dispense narcotics and other*
26 *controlled substances is required to receive public comment from*
27 *local law enforcement prior to establishing local protocols for*
28 *packaging, transporting, storing, and distributing narcotics and*
29 *other controlled substances.*

30 *(J) That local protocols established pursuant to this act*
31 *adhere to any applicable requirements established by the*
32 *California State Board of Pharmacy regarding packaging,*
33 *transporting, storing, and dispensing all prescription drugs,*
34 *including narcotics and controlled substances.*

35 *(K) That county protocols established for packaging,*
36 *transporting, storing, and dispensing medications that require*
37 *refrigeration, including, but not limited to, any biological*
38 *product as defined in Section 351 of the Public Health and*
39 *Service Act (42 U.S.C. Sec. 262), an intravenously injected drug,*
40 *or an infused drug, include specific procedures to ensure that*

1 *these medications are packaged, transported, stored, and*
2 *dispensed at their appropriate temperatures and according to*
3 *any applicable standards established by the California State*
4 *Board of Pharmacy.*

5 *(L) That, notwithstanding any other provision of law,*
6 *participating pharmacies adhere to the same procedural drug*
7 *pedigree requirements for donated drugs as they would for drugs*
8 *purchased from a wholesaler or directly from a drug*
9 *manufacturer.*

10 *(4) Ensuring the privacy of individuals for whom the*
11 *medication was originally prescribed.*